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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/488,298	01/20/2000	Olivier Lutz	3874-128 US	4242

7590 01/02/2004  
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EXAMINER

KIM, JENNIFER M

ART UNIT PAPER NUMBER

1617

DATE MAILED: 01/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/488,298

**Applicant(s)**

LUTZ ET AL.

**Examiner**

Jennifer Kim

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,4 and 7-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4,7-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_. 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The amendment filed October 29, 2003 have been received and entered into the application.

The rejection of claims 1, 18 and 20-21 of record under 35 U.S.C. 112, paragraph 1, is hereby expressly withdrawn in view of Applicants' amendment.

The rejection of claims 7, 8, 10 and 19 of record under 35 U.S.C. 112, paragraph 2, is hereby expressly withdrawn in view of Applicants' amendment.

Claims 1, 4 and 7-24 of record rejected under 35 U.S.C. 103 (a) over Lambert et al. (U.S. Patent No 6,458,373B1) is maintained for the reasons stated in the previous office action.

### ***Response to Arguments***

Applicants' arguments filed October 29, 2003 have been fully considered but they are not persuasive. Applicants argue that Applicants' claims are limited to compositions that require tocoferol wherein said tocoferol is limited to tocoferol covalently linked to a water-soluble polymer and that all composition contemplated within the disclosure of Lambert et al. '373, including Example 23, expressly require tocoferol, per se, as an

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independent chemical entity and that the '373 working example (23) does not indicate a formulation within the scope of the Applicants claims. This is not persuasive because Applicants formulation contained therein is indistinguishable with Lambert. For example, Applicants' formulation N comprises TPGS and formulation K by Lambert et al. comprises TPGS. (see page 5, Table 3). It is noted that Applicants claims are not drawn to specific TPG derivatives and it is noted that Applicants data are not directed to that specific TPG derivatives but are directed to composition comprising TPGS. (see table 3, Formulate N). Applicants' formulation N as is read on the formulation K since it is both formulations comprises TPGS as illustrated in Table 3 of the Rule 132 Declaration (page 5). Therefore, Applicants' alleged surprising unexpected result couldn't be justified by the same formulation illustrated in Table 3.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

In view of the above Office Action of August 26, 2003 is deemed proper and asserted with full force and effect herein to obviate applicants' claims.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4, 5, and 7-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lambert et al. (U.S. Patent No. 6,458,373 B1).

Lambert et al. teach a micelle solution or an emulsion with a particle size of 10 to 500 nm, preferably 10 to 200nm and most preferably 10 to 100 nm comprising chemotherapeutics including podophyllotoxins (etoposide) and their derivatives and analogues, tocopherol and TGPS (d- $\alpha$ -tocopherol polyethyleneglycol 1000 succinate). (abstract, column 3, lines 45-58, column 4, lines 1-3, column 7, lines 39-65, column 8, line 59, column 10, lines 28-33, column 21, Example 23).

Lambert et al. teach use of Applicants' water-soluble polymer, polyoxypropylene-polyoxyethylene copolymer in the above composition. (column 3, lines 59-64).

Lambert et al. teach use any compound including peptides, lipid conjugates/prodrugs, any natural or synthetic molecule which are slightly or completely

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lipophilic, and any molecules which stimulate the immune system in the above composition. (column 6, lines 54-56).

Lambert et al. teach the amounts of TPGS about 10% in the above composition. (column 21, Example 23).

Lambert et al. do not teach that tocopherol is covalently linked to a water-soluble polymer and the use of composition for treatment of cancer.

However, it would have been obvious to skill artisan to employ well known Lambert et al.'s composition in treatment of cancer since it is formulated with well known chemotherapeutical agent, etoposide and it's analogues in most desirable stable solution formulation. Further, one of ordinary skill in the art would have been motivated with reasonable expectation of success to formulate above composition further comprising any molecules including natural or synthetic since Lambert et al. teach their usefulness and the compatibility in the above composition in general.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

None of the claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 703-308-2232. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

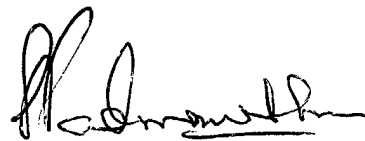
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 703-305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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Sreenivasan Padmanabhan  
Primary Examiner  
Art Unit 1617

12/28/03

Jmk

December 22, 2003